

50151



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	PATENT
	:	
Christian HUMMEL et al.	:	
	:	
Serial No.:	:	Art Unit: 3773
	:	
Filed:	:	Examiner: J. R. Ou
	:	
For:	:	Appeal No. _____
METHOD AND DEVICE FOR THE	:	
ENDOSCOPIC APPLICATION OF	:	
SELF-CLOSING MEDICAL CLIPS	:	

BRIEF ON APPEAL

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APPENDIX A – COPY OF CLAIMS ON APPEAL

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50151



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	PATENT
	:	
Christian HUMMEL et al.	:	
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Serial No.: 10/565,735	:	Art Unit: 3773
	:	
Filed: June 14, 2006	:	Examiner: J. R. Ou
	:	
For: METHOD AND DEVICE FOR THE	:	Appeal No. _____
ENDOSCOPIC APPLICATION OF	:	
SELF-CLOSING MEDICAL CLIPS	:	

APPELLANT BRIEF
ON APPEAL UNDER 37 C.F.R. §41.37

COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

For the appeal to the Board of Patent Appeals and Interferences from the decisions dated December 15, 2008 and March 13, 2009 of the Primary Examiner twice and finally rejecting claims 11-28 in connection with the above-identified application, Applicant-Appellant submits the following brief in accordance with 37 CFR §41.37.

1. Real Party in Interest

The inventors, Christian Hummel, Gerhard Emberger and Rudolf Bauer, assigned their entire rights, titles and interests in the patent application to Carl Stahl GmbH of Süssen, Germany and to Medwork Medical Products and Services GmbH of Höchstadt/Aisch, Germany.

2. Related Appeals and Interferences

There are no other related appeals or interferences known to Appellants, Appellants' legal representative, or assignees, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal.

3. Status of Claims

Claims 1-10 are cancelled. Claims 11-28 are pending, are rejected, and are on appeal.

4. Status of Amendments

Subsequent to the December 15, 2008 Office Action containing the final rejection, a February 4, 2009 Response was filed that did not seek to amend any claims. A March 13, 2009 Advisory Action considered the Response, but held that the Response did not place the application in condition for allowance.

5. Summary of Claimed Subject Matter

Independent claim 11 covers a method for endoscopic application of self-closing medical clips 3 comprising the steps of placing a distal end of a catheter tube 1 in a body of a living being to be treated, arranging at least one self-closing clip 3 with relatively movable legs 5 in the catheter tube adjacent the distal end by an operator located on a proximal end of the catheter tube, pushing the clip 3 out of the distal end, opening the clip 3 by an actuator 17, 21 having an actuating element 21 acting on the clip 3, being movable longitudinally in the catheter tube 1 and actuated by the operator and having a control part 33 converting an actuating force of the actuating element into a motion opening the legs 5 of the clip 3. The actuating element 21 is detached from the clip 3 after opening of the clip 3 to release the clip 3 and close the legs 5 of the

clip 3 to apply the clip 3. The clip 3 has a first kink 13 in a first area of each leg extending outwardly and increasing a distance between the legs 5 and a second kink 15 in a second area nearer the distal end 7 of the clip 3 than the first area, but spaced from that distal end, extending inwardly and forming a point of mutual support for the legs. Figs. 1 and 3-15; p. 7, line 21, to p. 8, line 24.

Independent claim 14 is directed to a device for endoscopic application of self-closing medical clips 3 in a body of a living being comprising a catheter tube 1, an operator, an actuator 21, 17 and at least one clip 3. The catheter tube has a distal end placeable in a body and a proximal end placeable outside the body. The operator is at the proximal end. Fig. 1; p. 6, lines 23-27. The actuator 21 extends in the catheter tube from the operator to an area adjacent the distal end, has an actuating element 17 movable longitudinally in the catheter tube and controlled by the operator, and has at least one control part with a distal end edge 25 on a sleeve-shaped receiving part 33. Figs. 1-13; p. 6, lines 18-27. The clip 3 is adjacent to and directly engages the distal end edge and has a part received in the actuating element 17 and two adjacent legs 5. Figs. 1 and 3-4; p. 6, lines 10-17. The legs 5 have first kinks 13 extending outwardly and increasing a distance between the legs 5 in first areas of the legs 5 and second kinks 15 extending inwardly and forming a mutual support for the legs 5 in second areas of the legs nearer to a distal leg end 7 of the clip 3 than the first area, but spaced from that distal end 7 without the legs crossing one another. Figs. 1-2; p. 5, line 23 to p. 6, line 9. The legs 5 are opened by the first kinks 13 engaging the control part when the clip 3 is inserted into the sleeve-like receiving part 33 which converts an actuating force of the actuating element 17 into an opening motion of the legs 5 with the second areas engaging one another. Figs. 1-4; p. 6, lines 10-17.

Independent claim 23 covers a self-closing medical clip 3 comprising a crosspiece 9, and first and second legs 5 extending adjacent to one another from the crosspiece 9 to distal ends 7 thereof and biased toward one another. The first kinks 13 in the legs 5 extend outwardly and increases a distance between the legs 5 in first areas of the legs. Second kinks 15 in the legs 5 extend inwardly and form a mutual support for the legs 5 in second areas of the legs 5. The second areas are nearer the distal ends 7 than the first areas. Figs. 1-2; p. 5, line 23 – p. 6, line 9.

By performing the method, forming the device and forming the clip in this manner, a simple and effective mechanism is provided in which the clips can be formed and then applied. The mutual support provided by the second kinks in the second areas allow the remaining portion of the legs to pivot outwardly when the first kink is compressed with the pivoting motion being initiated at the contact of the second kinks. None of the clips of the cited patents are formed or operated in this manner.

6. Grounds for Rejection to be Reviewed Upon Appeal

Claims 11-18, 20, 21 and 23-28 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Publication No. 2002/0128667 to Kobayashi.

Claims 19 and 22 are rejected under 35 U.S.C. §103(a) as being unpatentable over the Kobayashi publication in view of U.S. Patent Publication No. 2002/0045909 to Kimura.

7. Arguments

A. Rejection Under 35 U.S.C. §102 on Kobayashi Publication

(1) The Rejection

Claims 11-18, 20, 21 and 23-28 stand rejected under 35 U.S.C. §102 as being anticipated by U.S. Patent Publication No. 2002/0128667 to Kobayashi. A comparison of the cited

publication and the claimed subject matter is allegedly supported by the illustrations of Fig. 1' and Fig. 2' on pages 4 and 7 of the Office Action. In Fig. 1', the first bend below the crossover of the Kobayashi clip legs is alleged to provide the claimed first kink, and the bend near the distal end is alleged to provide the claimed second kink. The distal leg end is alleged to extend inwardly and form a point of mutual support for the leg to grip onto tissue, as allegedly shown in Fig. 21D of that patent. Relative to the limitation recited, for example in claim 16, of the pull cable extending through two adjacent holes in the rear end crosspiece connecting the clip legs, the rejection relies on the interpretation of Fig. 7C of the Kobayashi publication, along with Fig. 2' on page 7 of the Office Action. The first hole is interpreted as the center portion of ligating wire 10, and the second hole is interpreted as the recess of the outer surface of that ligating wire.

(2) Claim 11 is Patentably Distinguishable over the Kobayashi Publication

Claim 11 is patentably distinguishable over the Kobayashi publication by the method using a self-closing medical clip having a first kink extending outwardly and increasing the distance between the clip legs and a second kink extending inwardly and forming a point of mutual support for the clip legs, with the second kink being closer to the clip distal end than the first kink and being spaced from the clip distal end. This claimed use of this clip structure is not anticipated or rendered obvious by the Kobayashi publication, even under the improper interpretation of the Kobayashi clip structure proposed in the final Office Action and in the Advisory Action.

The final Office Action only relies on the embodiment of Figs. 21A through 21D of the Kobayashi publication. In this embodiment, the clips 14 are in an alpha shape with legs that cross one another. Specifically, the two legs are joined at a looped end and then converge toward and cross one another. After crossing, the two legs extend outwardly to a bend, alleged to

correspond to the claimed first kink. From that bend, the clip legs extend in a relatively longitudinal direction to an inwardly bent distal leg end, alleged to correspond to the claimed second kink. This clip configuration does not provide the first and second kinks in the legs, as claimed, particularly since the alleged second kink is at the distal end and not spaced therefrom and does not provide the claimed mutual support for the clip legs spaced from the distal end.

The comparison of the Kobayashi clip shown in Fig. 1' of the final Office Action (p. 4) does not satisfy the limitations of the clip recited in the claims. Specifically, the area designated as the second kink in the drawing of Fig. 1' is not spaced from the distal leg end and does not extend inwardly to form a point of mutual support for the legs that is spaced from the distal leg end. The alleged support relied upon in this rejection is only at the very distal end in the Kobayashi clip and is separated by tissue. In contrast, each claim requires that the mutual support be spaced from the distal end and provide a mutual support for the legs, not gripping the tissue. Only by providing this spacing of the mutual support from the distal end can the clip legs separate at the distal end upon compression of the clip of the first kinks.

The Advisory Action states:

The second kink in the drawing of Fig. 1 is obviously spaced from the leg end as shown and extends inward to form a point of mutual point mutual support for the legs to grip onto the tissue as shown in Fig. 21D.

However, claim 11 recites that the mutual support must also be spaced from the distal end. The mutual support alleged for the Kobayashi clip, if any, can only be at its distal end. The spacing of the mutual support from the end is ignored in the rejection, rendering it untenable.

Accordingly, claim 11 is not anticipated or rendered obvious by the Kobayashi publication.

(3) Claim 14 is Patentably Distinguishable over the Kobayashi Publication

Claim 14 is patentably distinguishable over the Kobayashi publication by the device comprising a self-closing medical clip having a first kink extending outwardly and increasing the distance between the clip legs and a second kink extending inwardly and forming a point of mutual support for the clip legs, with the second kink being closer to the clip distal end than the first kink and being spaced from the clip distal end. This claimed clip structure is not anticipated or rendered obvious by the Kobayashi publication, even under the improper interpretation of the Kobayashi clip structure proposed in the final Office Action and in the Advisory Action.

The final Office Action only relies on the embodiment of Figs. 21A through 21D of the Kobayashi publication. In this embodiment, the clips 14 are in an alpha shape with legs that cross one another. Specifically, the two legs are joined at a looped end and then converge toward and cross one another. After crossing, the two legs extend outwardly to a bend, alleged to correspond to the claimed first kink. From that bend, the clip legs extend in a relatively longitudinal direction to an inwardly bent distal leg end, alleged to correspond to the claimed second kink. This clip configuration does not provide the first and second kinks in the legs, as claimed, particularly since the alleged second kink is at the distal end and not spaced therefrom and does not provide the claimed mutual support for the clip legs spaced from the distal end.

The comparison of the Kobayashi clip shown in Fig. 1' of the final Office Action (p. 4) does not satisfy the limitations of the clip recited in the claims. Specifically, the area designated as the second kink in the drawing of Fig. 1' is not spaced from the distal leg end and does not extend inwardly to form a point of mutual support for the legs spaced from the distal leg end. The alleged support relied upon in this rejection is only at the very distal end in the Kobayashi clip and is separated by tissue. In contrast, each claim requires that the mutual support be spaced

from the distal end and provide a mutual support for the legs, not gripping the tissue. Only by providing this spacing of the mutual support from the distal end can the clip legs separate at the distal end upon compression of the clip at the first kinks.

The Advisory Action states:

The second kink in the drawing of Fig. 1 is obviously spaced from the leg end as shown and extends inward to form a point of mutual point mutual support for the legs to grip onto the tissue as shown in Fig. 21D.

However, claim 14 recites that the mutual support must also be spaced from the distal end. The mutual support alleged for the Kobayashi clip, if any, can only be at its distal end. The spacing of the mutual support from the end is ignored in the rejection, rendering it untenable.

Accordingly, claim 14 is not anticipated or rendered obvious by the Kobayashi publication.

(4) Claim 23 is Patentably Distinguishable over the Kobayashi Publication

Claim 23 is patentably distinguishable over the Kobayashi publication by the self-closing medical clip having a first kink extending outwardly and increasing the distance between the clip legs and a second kink extending inwardly and forming a point of mutual support for the clip legs, with the second kink being closer to the clip distal end than the first kink and being spaced from the clip distal end. This claimed clip structure is not anticipated or rendered obvious by the Kobayashi publication, even under the improper interpretation of the Kobayashi clip structure proposed in the final Office Action and in the Advisory Action.

The final Office Action only relies on the embodiment of Figs. 21A through 21D of the Kobayashi publication. In this embodiment, the clips 14 are in an alpha shape with legs that cross one another. Specifically, the two legs are joined at a looped end and then converge toward

and cross one another. After crossing, the two legs extend outwardly to a bend, alleged to correspond to the claimed first kink. From that bend, the clips extend in a relatively longitudinal direction to an inwardly bent distal leg end, alleged to correspond to the claimed second kink. This clip configuration does not provide the first and second kinks in the legs, as claimed, particularly since the alleged second kink is at the distal end and not spaced therefrom and does not provide the claimed mutual support for the clip legs spaced from the distal end.

The comparison of the Kobayashi clip shown in Fig. 1' of the final Office Action (p. 4) does not satisfy the limitations of the clip recited in the claims. Specifically, the area designated as the second kink in the drawing of Fig. 1' is not spaced from the distal leg end and does not extend inwardly to form a point of mutual support for the legs that is spaced from the distal leg end. The alleged support relied upon in this rejection is only at the very distal end in the Kobayashi clip and is separated by tissue. In contrast, each claim requires that the mutual support be spaced from the distal end and provide a mutual support for the legs, not gripping the tissue. Only by providing this spacing of the mutual support from the distal end can the clip legs separate at the distal end upon compression of the clip at the first kinks.

The Advisory Action states:

The second kink in the drawing of Fig. 1 is obviously spaced from the leg end as shown and extends inward to form a point of mutual point mutual support for the legs to grip onto the tissue as shown in Fig. 21D.

However, claim 23 recites that the mutual support must also be spaced from the distal end. The mutual support alleged for the Kobayashi clip, if any, can only be at its distal end. The spacing of the mutual support from the end is ignored in the rejection, rendering it untenable.

Accordingly, claim 23 is not anticipated or rendered obvious by the Kobayashi publication.

(5) Dependent Claims 12-13, 15-18, 20, 21 and 24-28 are
Patentably Distinguishable over the Kobayashi Publication

Claims 12-13 and 27, claims 15-18, 20, 21 and 28 and claims 24-26, being dependent upon claims 11, 14 and 23, respectively, are also allowable for the above reasons. Moreover, these dependent claims recite additional features further distinguishing them over the cited patents.

(a) Claim 12

Claim 12 is further distinguishable by the form of the legs, particularly the legs not crossing one another. The Kobayashi clip legs cross one another since the portion of that clip between the alleged “first kink” and ligating wire 10 cannot be ignored as providing portions of its legs that cross one another. The entirety of the Kobayashi clip legs must be considered. Eliminating or ignoring the looped end and cross overlap to consider only a “portion” of the Kobayashi clip results in a disjointed and inoperative structure that could not perform its clipping function due to the omission on the structure connecting the legs biasing the legs toward one another.

(b) Claim 13

Claim 13 is further distinguishable by the additional other clips and the functional linking of the various clips. Such clips are not provided in the Kobayashi publication, as noted above.

(c) Claim 15

Claim 15 is further distinguishable by the pulling element in combination with a beveled control surface on the distal end edge of the sleeve-shaped receiving part. No such beveled edge

is disclosed or rendered obvious by the Kobayashi publication. The Kobayashi tightening ring 29 in Fig. 19 is cited relative to the claimed receiving part for the first time in the Advisory Action. However, that ring does not have the beveled control surface at its distal end edge engaging the claimed clip. The mere possible presence of a bevel without any description in the specification of that publication also renders the rejection of claim 15 untenable.

(d) Claim 16

Claim 16 is further distinguishable by the crosspiece having the two adjacent holes, with the pull cable extending through those two holes. In contrast, Fig. 7C cited relative to this feature merely shows ligating wire 10 connecting manipulating wire 9 to clip 3 and having a notch or exterior recess therein. No crosspiece with two through holes is provided through which the manipulating cable 9 extends. Relative to the Office Action Fig. 2', the ligating ring is improperly interpreted as having two holes through which the pull wire extends. The Kobayashi manipulating wire 9 clearly does not extend through the exterior recess in ligating wire 10, as required by claim 16, a point not addressed in the final Office Action or the Advisory Action.

(e) Claim 17

Claim 17 is further distinguishable by the breaking point between the two through holes. Neither the crosspiece of the clip 3 nor wire 10 of the Kobayashi publication has the two through holes or the breaking point between those through holes. The exterior recess in Kobayashi ligating wire 10 cannot be properly interpreted to read on both a second hole and a breaking point, and does not receive wire 10.

(f) Claim 18

Claim 18 is further distinguishable by the blocking element recited therein, particularly within the overall combination with the claimed clip.

(g) Claim 20

Claim 20 is further distinguishable by the multiple clips with the second kinks, as claimed. Such clips are not disclosed in the Kobayashi publication.

(h) Claim 21

Claim 21 is further distinguishable by the actuator being a tube with the claimed clips, which clips are not disclosed in the Kobayashi publication.

(i) Claim 24

Claim 24 is further distinguishable by the legs not crossing one other. The legs of the Kobayashi publication cross one another, as noted above.

(j) Claim 25

Claim 25 is further distinguishable by the crosspiece having two holes adjacent one another with a predetermined breaking point therebetween which is not present in the Kobayashi clip, as discussed above.

(k) Claims 26-28

Each of claims 26-28 are further distinguishable by the bent distal ends spaced from the second kinks. Each of the recitations in these claims are not addressed in the Office Action. The alleged “second kinks” in the Kobayashi clips cannot be properly interpreted to be both the bent distal ends and the second kinks of these claims.

To support an anticipation rejection, all elements of the claim must be found in a single reference. In re Royka et al., 490 F.2d 981, 984, 180 USPQ 580, 582 (CCPA 1974). Rejections under 35 U.S.C. § 102 are proper only when the claimed subject matter is identically disclosed or described in the prior art. In re Marshall, 578 F.2d 301, 304, 198 USPQ 344, 346 (CCPA 1978). Since all elements of each of claims 11-18, 20, 21 and 23-28 are not identically disclosed or described in Kobayashi publication, the rejection of these claims under 35 U.S.C. § 102 is untenable.

B. Rejection Under 35 U.S.C. §103 over
Kobayashi Publication in View of Kimura Publication

(1) Claim 19

Claim 19 is further distinguishable by the blocking element being in the form of a collet with jaws. Relative to this feature, the Kimura publication is cited. However, it does not disclose the features in combination with the claim clip.

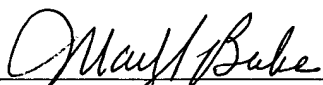
(2) Claim 22

Claim 22 is further distinguishable by the axial projection on the sleeve-shaped receiving part, particularly with the claimed clip in combination.

8. Conclusion

Accordingly, the rejections of claims 11-28 are untenable. Prompt and favorable action is solicited.

Respectfully submitted,



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Dated: April 28, 2009

APPENDIX A – COPY OF CLAIMS ON APPEAL

11. A method for endoscopic application of self-closing medical clips, comprising the steps of:

placing a distal end of a catheter tube in a body of a living being to be treated;

arranging at least one self-closing medical clip with relatively movable legs in the catheter tube adjacent the distal end by an operator located on a proximal end of the catheter tube, the clip having a first kink in a first area of each leg extending outwardly and increasing a distance between the legs and a second kink in a second area nearer a distal leg end of the clip than the first area but spaced from the distal leg end extending inwardly and forming a point of mutual support for the legs;

pushing the clip out of the distal end;

opening the clip by an actuator having an actuating element acting on the clip, being movable longitudinally in the catheter tube, being actuated by the operator and having a control part converting an actuating force of the actuating element into a motion opening the legs of the clip; and

detaching the actuating element from the clip after opening of the clip to release and close the legs of the clip to apply the clip.

12. A method according to claim 11 wherein

the legs of the clip are symmetrical, are mirror images of one another and do not cross one another.

13. A method according to claim 11 wherein

a plurality of other clips, similar to the one clip, are arranged in succession in the catheter tube; and

after application of the clip at the distal end of the catheter tube, the actuating device is functionally linked to the clip next following in the catheter tube.

14. A device for endoscopic application of self-closing medical clips in a body of a living being, comprising:

a catheter tube having a distal end placeable in the body and a proximal end placeable outside the body;

an operator at said proximal end;

an actuator extending in said catheter tube from said operator in an area adjacent said distal end, having an actuating element movable longitudinally in said catheter tube and controlled by said operator, and having at least one control part with a distal end edge on a sleeve-shaped receiving part; and

at least one clip adjacent to and directly engaging said distal end edge and having a part received in said actuating element and two adjacent legs, said legs having first kinks extending outwardly and increasing a distance between said legs in first areas of said legs and second kinks

extending inwardly and forming a mutual support for said legs in second areas of said legs nearer to a distal leg end of said clip than said first area, but spaced from said distal leg end without said legs crossing one another;

whereby said legs are opened by said first kinks engaging said control part when said clip is inserted into said sleeve-shaped receiving part which converts an actuating force of said actuating element into an opening motion of said legs with said second areas engaging one another.

15. A device according to claim 14 wherein

said actuating element comprises a pulling element; and

said distal end edge comprises a beveled control surface.

16. A device according to claim 15 wherein

said pulling element comprises a pull cable; and

said clip is connected to said pull cable by a rear end crosspiece connecting said legs of said clip, said rear end crosspiece having two adjacent through holes through which said pull cable extends in a loop connecting an advancing strand extending from said operator to said rear end crosspiece to a retreating strand extending to said operator from said rear end crosspiece.

17. A device according to claim 16 wherein

said rear end crosspiece comprises a section between said through holes forming a predetermined breaking point fracturable by a pulling force of said pull cable via said loop thereof to detach said pull cable from said clip.

18. A device according to claim 17 wherein

a blocking element is located on said distal end of said catheter tube, said blocking element permitting passage of said sleeve-shaped receiving part only in an exit direction forward from said catheter tube and supporting said sleeve-shaped receiving part against motion rearwardly into said catheter tube effected by the pulling force of said pull cable.

19. A device according to claim 18 wherein

said blocking element comprises a tube piece mounted on said distal end of said catheter tube and having an end part forming a collet with jaws extending longitudinally, said jaws normally biased to reduce a width of a passage through said collet in a normal position thereof, being elastically spreadable radially outwardly from the normal position by said sleeve-shaped receiving part passing through said passage and being returnable to the normal position to form a support for said sleeve-shaped receiving part against the pulling force of the pull cable after said sleeve-shaped receiving part emerged from said collet.

20. A device according to claim 16 wherein

at least one other clip and at least one other control part, similar to said one clip and said one control part, respectively, are mounted in succession with said one clip and said one control part in said catheter tube; and

said advancing strand and said retreating strand extend through respective through holes in a rear end crosspiece joining legs of said other clip.

21. A device according to claim 16 wherein

said actuator comprises a tube movable in said actuator tube and having an end edge forming a plunger contacting a facing back end of said sleeve-shaped receiving part.

22. A device according to claim 19 wherein

sleeve-shaped receiving part comprises a back end opposite said beveled control surface with an axially projecting shoulder receivable in said collet to center said sleeve-shaped receiving part relative to said blocking element.

23. A self-closing medical clip, comprising:

a crosspiece;

first and second legs extending adjacent one another from said crosspiece to distal ends thereof and biased toward one another;

first kinks in said legs extending outwardly and increasing a distance between said legs in first areas of said legs; and

second kinks in said legs extending inwardly and forming a mutual support for said legs in second areas of said legs, said second areas being nearer said distal ends than said first areas but being spaced from said distal ends.

24. A self-closing medical clip according to claim 23 wherein

said legs do not cross one another.

25. A self-closing medical clip according to claim 23 wherein

said crosspiece has two adjacent through holes with a predetermined breaking point extending therebetween.

26. A self-closing medical clip according to claim 23 wherein

said distal ends of said legs are bent toward one another at a location spaced from said second kinks.

27. A method according to claim 11 wherein

distal ends of the legs are bent toward one another at a location spaced from said second kinks.

28. A device according to claim 14 wherein

distal ends of said legs are bent toward one another at a location spaced from said second kinks.

APPENDIX B - EVIDENCE

None.

APPENDIX C – RELATED PROCEEDINGS

None.